EMA/717745/2013

European Medicines Agency decision

P/0312/2013

of 19 December 2013

on the acceptance of a modification of an agreed paediatric investigation plan for aciclovir (Sitavig and associated names) (EMEA-001066-PIP02-11-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for aciclovir (Sitavig and associated names) (EMEA-001066-PIP02-11-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/233/2011 issued on 26 September 2011,

Having regard to the application submitted by BioAlliance PHARMA on 13 August 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 November 2013, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for aciclovir (Sitavig and associated names), muco-adhesive buccal tablet, gingival use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to BioAlliance PHARMA, 49 Boulevard du Général Martial Valin,75015 – Paris, France.

Done at London, 19 December 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/538702/2013

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001066-PIP02-11-M01

Scope of the application

Active substance(s):

Aciclovir

Invented name:

Sitavig and associated names

Condition(s):

Treatment of herpes simplex labialis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Muco-adhesive buccal tablet

Route(s) of administration:

Gingival use

Name/corporate name of the PIP applicant:

BioAlliance PHARMA

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, BioAlliance PHARMA submitted to the European Medicines Agency on 13 August 2013 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/233/2011 issued on 26 September 2011.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 12 September 2013.

A meeting with the Paediatric Committee took place on 07 November 2013.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

London, 8 November 2013

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

1.1. Condition: Treatment of herpes simplex labialis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 10 years of age;
- for muco-adhesive buccal tablet, gingival use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of herpes simplex labialis

2.1.1. Indication(s) targeted by the PIP

Treatment of recurrent herpes simplex virus infections of the lips in immunocompetent children aged 10 to less than 18 years

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 10 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Muco-adhesive buccal tablet

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Open-label, single dose trial to evaluate compliance, salivary pharmacokinetics and acceptability, palatability and local tolerance of aciclovir muco-adhesive buccal tablets in children from 10 to less than 18 years of age.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of herpes simplex labialis

Authorised indication(s):

- Treatment of recurrent herpes labialis in immunocompetent adults with frequent herpes episodes

Authorised pharmaceutical form(s):

Muco-adhesive buccal tablet

Authorised route(s) of administration:

Gingival use